NuVasive Specialized Orthopedics, Inc.
Madison Heffron
Regulatory Affairs Specialist
101 Enterprise
Suite 100
ALISO VIEJO, CA 92656

May 8, 2020

Re: K193016
Trade/Device Name: PRECICE® Bone Transport System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: April 7, 2020
Received: April 9, 2020

Dear Madison Heffron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and

regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193016

Device Name

PRECICE® Bone Transport System

Indications for Use *(Describe)*

The PRECICE® Bone Transport System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRECICE® Bone Transport System
510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Madison Heffron
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (949) 532-7868

Date Prepared: May 7, 2020

B. Device Name

Trade or Proprietary Name:	*PRECICE® Bone Transport System*
Common or Usual Name:	Intramedullary Fixation Rod
Classification Name:	Rod, Fixation, Intramedullary and Accessories; Screw, Fixation, Bone
Device Class:	Class II
Classification:	21 CFR § 888.3020
Product Code (primary):	HSB
Product Code (subsequent):	HWC (screw, fixation, bone)

C. Predicate Devices

The subject *PRECICE® Bone Transport System* is substantially equivalent to the primary predicate device, *PRECICE® Bone Transport System* (K182170).

D. Device Description

The PRECICE® Bone Transport System includes the PRECICE® Bone Transport Nail, locking screws, end caps, surgical instruments, and external remote controller (ERC). The PRECICE® Bone Transport nails and end caps are supplied sterile by gamma radiation while the locking screws and instruments are supplied non-sterile and must be sterilized prior to use. The system is designed to achieve limb correction through gradual lengthening or compression of the intercalary bone segment and providing internal fixation for fractures of long bones. The PRECICE® Bone Transport intramedullary nail is implanted using locking screws, end caps, and reusable surgical instruments. The PRECICE® Bone Transport nail contains an enclosed rare earth magnet, distraction rod, and planetary gearing which allows the extension of the distraction rod to be adjusted non-invasively by the External Remote Controller (ERC). The PRECICE® Bone Transport nail is available in various diameters, lengths and screw hole configurations to accommodate a variety of patient anatomies and implantation methods. The locking screws are

also available in a variety of diameters, lengths, and thread styles. The ERC is available in several compatible models.

The purpose of this submission is to introduce additional compatible locking screws to the system.

E. Indications for Use

The PRECICE® Bone Transport System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

F. Comparison of Technological Characteristics with the Predicate Device

As was established in this submission, the subject PRECICE® Bone Transport System is substantially equivalent to the predicate PRECICE® Bone Transport System (K182170) previously cleared by the FDA for commercial distribution in the United States. There have been no design changes to the implants previously cleared in the predicate 510(k)s. The subject device has been shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

Nonclinical performance verification testing was performed to demonstrate that the subject PRECICE® Bone Transport System is substantially equivalent to the predicate device. The following testing was performed:

<table>
<tr><th>Testing Description</th><th>Applicable Standard</th></tr>
<tr><td>Static Compression Bending Strength</td><td rowspan="3">ASTM F1264 - Standard Specification and Test Methods for Intramedullary Fixation Devices</td></tr>
<tr><td>Dynamic Compression Bending strength</td></tr>
<tr><td>Torsion</td></tr>
<tr><td>Torque Resistance</td><td rowspan="2">ASTM F543 - Standard Specification and Test Methods for Metallic Medical Bone Screws</td></tr>
<tr><td>Axial Pullout</td></tr>
<tr><td>Distraction Force</td><td>N/A</td></tr>
</table>

The results demonstrate that the subject PRECICE® Bone Transport System is substantially equivalent to the predicate.

H. Conclusions

The subject PRECICE® Bone Transport System has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.